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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,506	12/19/2005	Andreas Meinke	SONN:085US/10512514	6550

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EXAMINER	
OGUNBIYI, OLUWATOSIN A	
ART UNIT	**PAPER NUMBER**
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,506	MEINKE ET AL.	
	Examiner	Art Unit	
	Oluwatosin Ogunbiyi	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-41,43,45,47-51 and 53-56* is/are pending in the application.

4a) Of the above claim(s) *53-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36, 39,43, 45 and 47-51* is/are rejected.

7)☒ Claim(s) *37,38,40,41,45 and 51* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

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The amendment filed 9/4/07 has been entered into the record. Claims 1-35, 42, 44, 46 and 52 have been cancelled. Claims 36-41, 43, 45, 47-51 and 53-56 are pending. Claims 36-41, 43, 45 and 47-51 are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

Double Patenting

1. The statutory basis for a statutory type 35 U.S.C. 101 rejection cited in the office action filed 3/6/07 was made in error and no double patenting rejection was made.

Claim Objection

2. The objection to claims 42-44, 51 and 52 under 37 CFR 1.75 as being a substantial duplicate thereof of claim 36 is withdrawn.

3. The objection claims 42,44, 46 and 52 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn.

Claim Rejections - 35 USC § 101

4. The rejection of Claims 36-52 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of the amendment to the claims and in view of the cancellation of claims 42, 44, 46 and 52.

Claim Rejections - 35 USC § 112

5. The rejection of claims 43-50 and 52 under 35 U.S.C. 112, first paragraph is withdrawn in favor of a new rejection set forth below.

6. The rejection of claims 42, 44, 46 under 35 U.S.C. 112, second paragraph is withdrawn in view of the cancellation to the claims.

Claim Rejections - 35 USC § 102 and 103

7. The rejection of claims 36-42 under 35 U.S.C. 102(b) as being anticipated by Read et al. Nucleic Acids Research, vol. 28, p. 1397-1406, 2000 as evidenced by Chlamydia pneumoniae AR39 complete genome accession number AE002161 (publicly available Jan 9, 2001) and Chlamydia pneumoniae AR39 hypothetical protein CP_ 0271 accession number AAF38131 (publicly available March 7, 2000) is withdrawn in view of the amendment to the claims and the cancellation of claim 42.

8. The rejection of claims 43-48, 51-52 under 35 U.S.C. 102(b) as being anticipated by Murdin et al. The Journal of Infectious Diseases 2000; 181 (Suppl 3):S544-51 as evidenced by Chlamydia pneumoniae AR39 complete genome accession number AE002161 (publicly available Jan 9, 2001) and Chlamydia pneumoniae AR39 hypothetical protein CP_ 0271 accession number AAF38131 (publicly available March 7, 2000 is withdrawn in view of the amendment to the claims and the cancellation of claims 44, 46 and 52.

9. The rejection of claims 43-44, 47-52 under 35 U.S.C. 103(a) as being unpatentable over Read et al. Nucleic Acids Research, vol. 28, p. 1397-1406, 2000 as evidenced by Chlamydia pneumoniae AR39 complete genome accession number

AE002161 (publicly available Jan 9, 2001) and Chlamydia pneumoniae AR39 hypothetical protein CP_ 0271 accession number AAF38131 (publicly available March 7, 2000) in view of Meinke et al, WO 02/059148, Aug. 1 2002 is withdrawn in view of the amendment to the claims and the cancellation of claims 44,46 and 52.

10. The rejection of claims 43-52 under 35 U.S.C. 103(a) as being unpatentable over Murdin et al, The Journal of Infectious Diseases 2000; 181 (Suppl 3):S544-51 as evidenced by as evidenced by Chlamydia pneumoniae AR39 complete genome accession number AE002161 (publicly available Jan 9, 2001) and Chlamydia pneumoniae AR39 hypothetical protein CP_ 0271 accession number AAF38131 (publicly available March 7, 2000) in view of Meinke et al, WO 02/059148, Aug. 1 2002 is withdrawn in view of the amendment to the claims and the cancellation of claims 44, 46 and 52.

Rejections/Objections Maintained

11. The objection of claim 45 and 51 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is maintained for reasons made of record in the previous office action filed 3/6/07.

Applicants' argument has been carefully considered but is not persuasive.

Claim 45 is drawn to the pharmaceutical composition of claim 43 comprising at least two different hyperimmune serum reactive antigens and/ or fragments.

The recitation of "further defined as" as written in the claim does not further limit the product of claim 43 properly. Applicants may amend claim 45 provided there is support in the specification for such an amendment by reciting "further comprising".

The recitation of "further defined as a vaccine" in claim 51 is an intended use and does not further limit the structure of the pharmaceutical composition of claim 43 from which claim 51 depends.

New Rejections Based on Amendment

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 36, 39, 43, 45, 47, 48 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Breton et al US 6,562,958 B1, May 13, 2003. Filed June 4, 1999 as application number 09/328,352.

The claims are drawn to an isolated hyperimmune serum reactive antigen comprising an amino acid sequence consisting of a fragment of SEQ ID NO: 91.

Breton et al teaches an isolated immunogenic component/antigen (SEQ ID NO: 4452 and see attached sequence alignment) comprising an amino acid sequence which consists of a fragment of SEQ ID NO: 91 (see column 8 lines 54-65, table 2 columns 93 and 94). Said isolated antigen of Breton et al meets the structural limitations of the claim, thus said antigen or immunogenic component of which comprises an amino acid sequence which consists of a fragment of SEQ ID NO: 91 is also hyperimmune serum reactive absent evidence to the contrary and in view of the recitation of immunogenic by

Breton et al. Said isolated immunogenic component comprises at least 6 contiguous amino acids of SEQ ID NO: 91 (See alignment). Breton et al teaches said immunogenic component as a pharmaceutical composition (column 37 lines 60-65) wherein in said composition further comprises other immunogenic components (i.e. one or more immunogenic components/at least two antigens) (column 37 lines 60-65). Said composition further comprises an immunostimulatory substance such as aluminum hydroxide (alum) or cholera toxin. The recitation of 'vaccine' in instant claim 51 is an intended use of the claimed product and does not structurally distinguish the claimed product from the product of the prior art and therefore is not given patentable weight for the claimed product. See MPEP 2111.02

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 36, 39, 43,45 and 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breton et al US 6,562,958 B1, May 13, 2003. Filed June 4, 1999 as application number 09/328,352 in view of Meinke et al, WO 02/059148, Aug. 1 2002.

The claims are drawn to an isolated hyperimmune serum reactive antigen comprising an amino acid sequence consisting of a fragment of SEQ ID NO: 91.

Breton et al teaches an isolated immunogenic component/antigen (SEQ ID NO: 4452 and see attached sequence alignment) comprising an amino acid sequence which consists of a fragment of SEQ ID NO: 91 (see column 8 lines 54-65, table 2 columns 93 and 94). Said isolated antigen of Breton et al meets the structural limitations of the claim, thus said antigen or immunogenic component of which comprises an amino acid sequence which consists of a fragment of SEQ ID NO: 91 is also hyperimmune serum reactive absent evidence to the contrary and in view of the recitation of immunogenic by Breton et al. Breton et al teaches said immunogenic component as a pharmaceutical composition (column 37 lines 60-65). Said composition further comprises an immunostimulatory substance such as aluminum hydroxide (alum) or cholera toxin.

Breton et al does not teach immunostimulatory substances such as polycationic polymer, polycationic peptide, neuroactive compound, immunostimulatory deoxynucleotides, Freund's complete adjuvants, Freund's incomplete adjuvants, neuroactive compounds such as growth human growth hormone,

Meinke teach examples of suitable auxiliary substances such as buffer substances, stabilizers or further active ingredients known in connection of vaccine production. Meinke teach that a preferable carrier/ or excipient is an immunostimulatory compound for further stimulating the immune response to said hyperimmune serum reactive antigen. Meinke teach said immunostimulatory compounds such as polycationic substances, especially polycationic peptides, immunostimulatory

deoxynucleotides, alum, Freund's complete adjuvants, Freund's incomplete adjuvants, neuroactive compounds, especially human growth hormone, a peptide containing at least 2 lysleulys motifs (2 KLK-motifs) or combinations thereof.

It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to use in the pharmaceutical preparation of Breton et al other types immunostimulatory substances as taught by Meinke et al because Meinke et al teach that said immunostimulatory substances are used to further stimulate the immune response to an antigen, thus resulting in the instant invention with a reasonable expectation of success. It would also have been prima facie obvious to one of ordinary skill in the vaccine art to try any of the known immunostimulatory substances of the vaccine art said substances taught by Meinke et al.

New Rejections/Objections

Claim Objections

14. Applicant is advised that should claim 37 be found allowable, claim 38 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 37 recites " The isolated hyperimmune serum reactive antigen or fragment...further defined as a peptide consisting of an amino acid sequence described in: the "predicted immunogenic aa," "Predicted class II restricted T-Cell epitopes/regions," "Predicted class I restricted T-Cell epitope/regions," and/or "location of identified immunogenic region" column of Table 1A or 1C or in Table 2.

Claim 38 is also drawn to the isolated hyperimmune serum reactive antigen or fragment...further defined as a peptide consisting of an amino acid sequence

described in the tables of claim 37 (see specification p. 63 SEQ ID NO: 91 for predicted immunogenic aa: 4-10, 16-28, 3-14, 16-30, 2-16 under the headings "predicted immunogenic aa," "Predicted class II restricted T-Cell epitopes/regions," "Predicted class I restricted T-Cell epitope/regions," and/or "location of identified immunogenic region" and table 2 p. 68 SEQ ID NO:91).

15. Claims 37, 38, 40 and 41 are objected to as being dependent on rejected claim 36.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claim 43, 45 and 47-51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic pharmaceutical composition comprising an antigen comprising an amino acid sequence consisting of SEQ ID NO: 91 or a fragment thereof, does not reasonably provide enablement for a pharmaceutical composition comprising an antigen comprising an amino acid sequence consisting of SEQ ID NO: 91 or a fragment thereof further defined as a vaccine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The nature of the invention is drawn to a pharmaceutical composition comprising an isolated hyperimmune serum reactive antigen comprising an amino acid sequence consisting of SEQ ID NO: 91 or a fragment thereof further defined as a vaccine.

The specification teaches that pharmaceutical compositions of SEQ ID NO:91 or a fragment thereof are to be used as a vaccine (p. 36 paragraphs 3-5).

The specification teaches the identification of predicted immunogenic antigens e.g. SEQ ID NO: 91 and fragments of SEQ ID NO: 91 by using a screening method that uses serum from *Chlamydia* infected patients on a *C. pneumoniae* genomic expression library. The specification on p. 14 teaches that antibodies produced against *Chlamydia* by the human immune system and present in human sera are indicative of the *in vivo* expression of the antigenic proteins and their immunogenicity. The specification further predicts the epitopes contained in SEQ ID NO: 91 that are immunogenic (p. 48 example 5, table 51 SEQ ID NO: 91).

However, the specification does not correlate the immunogenicity of SEQ ID NO: 91 and predicted epitopes (fragments of SEQ ID NO: 91) with a protective immune response against *C. pneumoniae*. There is no challenge data in an animal model that provides evidence for a vaccine or prophylaxis (prevention) against infection by *C. pneumoniae*. The specification teaches that SEQ ID NO: 91 is immunogenic and predicts immunogenic epitopes (or hyperimmune serum reactive) fragments of SEQ ID NO: 91; however immunogenicity does not predict a protective immune response.

Vaccines induce protection against infections by stimulating the development of long-lived effector cells and memory cells (Abbas et al. Cellular and Molecular Immunology 4th edition chapter 15 p. 360-362, 2000). Vaccines by definition trigger an immunoprotective response in the host vaccinated and mere antigenic response i.e. immunogenicity is insufficient. It is well recognized in the vaccine art, that it is unclear whether an antigen(s) derived from a pathogen will elicit protective immunity. Ellis, R.W. (Chapter 29 of "VACCINES" [Plotkin, S.A. et al. (eds) published by W. B. Saunders company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem (of vaccine development) is

the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies.... and thus protect the host against attack by the pathogen". In the instant case, the specification has not correlated the production of protective antibodies via active immunization with the claimed proteins with protection against *C. pneumoniae* in order to result in a vaccine or prophylactic treatment of an infection. Testing Chlamydia proteins identified by genomics and proteomics in an *in vivo* model where correlates of immunological protection can be examined provides a powerful combination for effective vaccine design (Thorpe et al. Vaccine vol. 25 p. 2252-2260, 2007). The art teaches that vaccine candidate antigens for *C. pneumoniae* are further tested in an animal model of infection to study induction of immunity and to correlate with protection from infection (Puolakkainen et al. Life Sciences vol. 322, p. 973-978 1999, Thorpe et al. Vaccine vol. 25 p. 2252-2260, 2007). Thus, it is therefore unpredictable that SEQ ID NO: 91 or fragments thereof will provide a protective immune response in vivo. The art also teaches that chlamydia subunit vaccine candidates that have demonstrated immunogenicity in vitro provide poor immunogenicity in vivo and consequently producing only partial protective immunity and antigen selection based solely on recognition by antibodies will likely not be suitable for inducing protective immunity against Chlamydia (Igietseme et al Expert Rev. Vaccines 2 (1), 129-146, 2003. See p. 135 columns 1 and 2).

In view of the nature of the invention, lack of guidance presented in the specification and the absence of examples correlating the induction of a protective immune response to a pharmaceutical composition comprising a hyperimmune serum reactive antigen comprising SEQ ID NO: 91 and a fragment of amino acid of SEQ ID NO:91 with prevention of *C.pneumoniae* infection (vaccine), the unpredictability as to whether said Seq ID NO: 91 and a fragment thereof will induce a protective immune response, and the teachings of the vaccine art, undue experimentation will be required of the skilled artisan to practice the invention as claimed.

Applicants' argument asserting the immunogenicity of Seq ID NO: 91 and fragments thereof disclosed in the specification are persuasive however the claims are not enabled with respect to a vaccine as set forth supra.

Status of Claims

Claims 37-38 and 40-41 are free of art. Claims 37-38, 40-41, 45 and 51 are objected to. Claims 36, 39, 43, 45, 47-51 are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Oluwatosin Ogunbiyi whose telephone number is 571-272-9939. The examiner can generally be reached on M-F 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Shanon Foley can be reached on 571-272-0898.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Oluwatosin Ogunbiyi
Examiner
Art Unit 1645

SHANON FOLEY
SUPERVISORY PATENT EXAMINER
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